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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,794	10/04/2002	Leif Andersson	11145-023US1	9287
7590 03/01/2006			EXAMINER	
Fish & Richardson Suite 3300 60 South Sixth Street Minneapolis, MN 55402			MONSHIPOURI, MARYAM	
			ART UNIT	PAPER NUMBER
			1653	
			DATE MAILED: 03/01/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,794

Applicant(s)

ANDERSSON ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>filed 10/02</u> . | 6) <input type="checkbox"/> Other: ____. |

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Applicant's response to restriction requirement filed 12/19/2006 is acknowledged. Applicant elected Group II(a) invention directed to claims 11-17, 21-23, 26-28 drawn to SEQ ID NO:4, 32 and 30, with traverse.

In traversal of restriction requirement applicant argues that all sequences Groups IIa-b are AMPK sequences and have significant structural and functional similarities because SEQ ID NO:s 2 and 4 are 97.05% identical and SEQ ID NO:s 28 and 30 are 85.99% identical. Therefore said groups should be rejoined.

These arguments were fully considered but were found **unpersuasive** because applicant is well aware that SEQ ID NO:2 and 28 are porcine AMPKs while SEQ ID NO:4 and 30 are human AMPKs. The fact that porcine and human AMPKs are not structurally identical (i.e. 100% identical) suggest that in contrast to applicant's view the function of said products must be significantly different in nature, rendering them subject to lack of unity as stated previously. Therefore, the examiner finds no reason to withdraw lack of unity between Groups IIa-b.

In addition, upon further review of the previous office action it appears that Group II(a) should have been merely directed to claims 22-23 as these are the only claims directed to SEQ ID NO:4 and 30. The examiner also agrees with the applicant that SEQ ID NO:32 must have been rejoined with Group II(a) instead of Group II(b) and regrets any inconveniences that said inadvertent errors may have caused the applicant.

DETAILED ACTION

Claims 22-23 drawn to a method of use of DNA sequences encoding isolated human muscular AMPK and a splice variant thereof (SEQ ID NO:4 and 32) are under

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examination on the merits. Claims 1-21, 24-25 and 26-33 are withdrawn as drawn to non-elected invention.

Claim Objections

Claims 22-23 are objected to because of the following informalities: Said claims still depend from non-elected invention claim 21 (SEQ ID NO:2, 28 and 32). Applicant is advised to rewrite said claims and delete non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "specific hybridization" in claim 23 is unclear.

Applicant is page 11 of the disclosure has attempted to define said term. However said definition is unclear because stringent conditions is not explicitly defined in terms of salt and temperature conditions. Therefore the skilled artisan does not know which salt and temperature conditions to utilize in order to practice the claimed method.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "functionally altered allele" in claim 22 and its dependent claim 23 is unclear. In pages 7-9 applicant attempts to define said term in the disclosure. However, said definition is unclear because it is indefinite how for

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example, R41Q variant in both SEQ ID NO:4 (305 amino acids) and 30 (464 amino acids), which are of different length has a mutation in an identical position 41.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting a metabolic disorder correlated with an altered glycogen accumulation in muscular cells of a vertebrate which results from the expression of a functionally altered allele of human gamma subunit of AMPK, SEQ ID NO:4 comprising contacting the nucleic acid sample from a vertebrate with a nucleic acid probe spanning mutations associated with said functionally altered allele in the first CBS domain, does not reasonably provide enablement for a method of detecting a metabolic disorder correlated with an altered glycogen accumulation in muscular cells of a vertebrate which results from the expression of a functionally altered allele of SEQ ID NO:30, comprising contacting the nucleic acid sample from a vertebrate with a nucleic acid probe spanning mutations associated with said functionally altered allele and detecting the hybridization complex.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples,

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4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The disclosure in page 9 only attempts to define the regions in SEQ ID NO:4 wherein mutations responsible for functional alterations are located and refers to region spanning residues 30-50 SEQ ID NO:4. More specifically the disclosure refers to R-Q and V-I substitution in said region, which is also referred to as the first CBS domain. No information about equivalent regions in SEQ ID NO:30 is provided. Applicant is well aware that the region spanning residues 30-50 of variant human AMPK gamma subunit cannot be identical to that region of SEQ ID NO:4. Further, figure 3 is confusing firstly because it displays the CBS1 domain as starting at residue 72 of SEQ ID NO:4 (HumG3) which is past residues 30-50 and secondly, no alignment of SEQ ID NO 30 or any indication of regions in which functionally altered alleles of SEQ ID NO:30 occur is provided. Therefore, it is believed that the disclosure fails to teach any functionally altered alleles of SEQ ID NO: 30 or any probe structures spanning said altered alleles. No examples of a probe to be utilized in detecting such alleles are provided either. Current state of prior art is totally unpredictable as to which probes are likely to span the altered alleles of SEQ ID NO:30.

Therefore, due to lack of sufficient teachings and examples provided in the disclosure and due to unpredictability of prior art as to which probes of what length and structure are likely to hybridize to DNA sequences encoding functionally altered mutants of SEQ ID NO:30 one of skill in the art has to go through the burden of undue experimentation in order to practice the claimed method.

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No claims are allowed.

Allowable Subject Matter

DNA sequences encoding the complete amino acids sequences of SEQ ID NO:4 and 30 are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed sequences. Hence, said DNA sequences are also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maryam Monshipouri Ph.D.
Primary Examiner
